MCP-279

Docket No. MCP-0279

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	McTeigue et al.	
Serial No.	:	09/878,034	Art Unit: 1615
Filed	:	June 8, 2001	Examiner: A. E. Pulliam
For	:	Taste Masked Pharmaceutical Particles	

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November 20, 2003
(Date of Deposit)

Sharon B. Hayner
Name of applicant, assignee, or Registered Representative

(Signature)

November 20, 2003
(Date of Signature)

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

Real Party in Interest

The real party in interest is McNeil-PPC, Inc., the assignee of the application.

Related Appeals and Interferences

None.

Status of the Claims

Claims 1-9 and 11-24 are pending herein and have been finally rejected in the Office Action mailed March 31, 2003. Claims 10 and 25 have been cancelled.[1]

Status of Amendments

No amendments to the claims have been filed subsequent to the final rejection.

[1] The Office Action of March 31, 2003 rejected claims 1-25. However, it is believed this is a typographical error, in that claims 10 and 25 were cancelled in applicant's Amendment mailed January 21, 2003.

Summary of the Invention

The present invention relates to a taste masked particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

The invention also relates to a chewable tablet comprising taste masked particles, each particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

Finally, the invention further relates to a method of taste masking particles comprising an active ingredient, which comprises applying a continuous polymeric coating over said particles, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

Issues

1. Whether claims 1-9 and 11-24 are obvious under Section 103 over Canadian Appln. No. 2,068,366 to Morella et al.

Grouping of Claims

The claims are grouped separately for purposes of this appeal as follows: 1) claims 1-9 and 11-18 relating to a taste masked particle and chewable tablet containing the same; and 2) claims 19-24 relating to a method of taste masking particles.

Argument

All of the pending claims have been rejected as obvious over Morella. The Examiner argues this reference discloses a taste masked, free flowing powder including microcapsules, in which each microcapsule includes a core including an active ingredient, and a substantially smooth and continuous microcapsule coating that contains a water insoluble polymer and optionally an enteric polymer. The Examiner further argues that Morella discloses chewable tablets. The Examiner maintains all of the features of applicants' dependent claims are also disclosed.

Applicants maintain the rejection of record is without merit. Morella describes a microcapsule composition and process for making the same. The Morella microcapsules comprise an effective amount of a core element comprising a pharmaceutically active ingredient and a coating on the core element. The coating is applied as a solution by spray drying. The coating solution contains 3 to 75 wt % of a water insoluble polymer. The coating solution may also optionally contain an enteric, reverse enteric, or water soluble polymer, but it need not. Importantly, the dissolution profile of the microcapsule is reduced by approximately 25%, preferably approximately 40%, more preferably approximately 50%, relative to a standard microencapsulated tablet when measured at a pH of about 6.8.

In contrast to Morella, the claimed invention achieves an immediate release dissolution profile. That is, at least 80% of the active ingredient is dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and at least 70% of the active ingredient is dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.[2] Achievement of an

[2] The Examiner argues that applicants' claims do not recite an immediate release dissolution profile, however, recitation of the actual dissolution behavior under stated conditions amounts to the same thing.

immediate release dissolution profile is an aim of the invention. See page 7, lines 16-25 of the specification. And it is neither taught nor suggested by Morella.

In Example 3 of Morella, arguably the closest disclosure in Morella, sodium diclofenac was coated with a coating solution of ethylcellulose, hydroxypropyl methylcellulose acetate succinate and dicloromethane. The coating was applied by spray drying. However, the resulting product, by Morella's own admission, gave "a typical enteric release profile." Page 19, lines 18-20. The release profile of the diclofenac is shown in Figure 3, which indicates that less than 80 % of the drug had been released after 30 minutes in a pH 7.5 solution.

The Examiner argues that Morella's Example 3 data cannot be fairly compared with the dissolution standard set forth applicants' claims, in that applicants' claims call for testing at a pH of 7.2, while Morella's dissolution in Example 3 was run at a pH of 7.5 (Figure 3). Applicants disagree. This difference in pH is slight. One skilled in the art would not, contrary to the Examiner's assertion, expect different behavior at these two pH's. The data is compelling as it is. Morella does not teach or suggest a combination of water insoluble film forming polymers and enteric polymers to obtain immediate release-type dissolution profiles.

As for claims 19-24, Morella does not teach or suggest a combination of water insoluble film forming polymers and enteric polymers to taste mask. Although Morella refers to the microparticles disclosed therein as a taste-masked, free flowing powder, use of applicants' specific polymer combination to taste mask is not found in Morella. Moreover, although Morella states that their particles are "smooth and continuous," they cannot be. They are prepared by spray drying, which, as taught in applicants' specification on page 6, first paragraph, in fact results in a matrix of active ingredient and coating material. The matrix is porous and contains active ingredient exposed on its surface. Spray drying is therefore inferior for taste masking. Applicants' claims require a "continuous" polymeric coating, which cannot be achieved by Morella.

At a minimum, claims 19-24 directed to a method of taste masking are neither taught nor suggested by Morella. Applicants also maintain the data in Morella shows that

the Morella microcapsules do not have an immediate release dissolution profile. Accordingly, claims 1-9 and 11-18 are also patentable.

Conclusion

For these reasons, a reversal of the rejection of record is respectfully requested.

Please charge Deposit Account No. 10-0750/MCP-279/SEH in the name of Johnson & Johnson all fees required in connection with this paper. This Authorization is being submitted in triplicate.

Respectfully submitted,

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APPENDIX
CLAIMS ON APPEAL

1. A taste masked particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

2. The particle of claim 1, wherein the surface of said particle is substantially free of active ingredient.

3. The particle of claim, wherein the coating is substantially free of plasticizer.

4. The particle of claim 1, wherein the active ingredient is a nonsteroidal anti-inflammatory drug.

5. The particle of claim 1, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate and cellulose acetate phthalate.

6. (amended) The particle of claim 1, wherein the water insoluble film forming polymer is selected from the group consisting of cellulose acetate and ethylcellulose.

7. The particle of claim 1 further comprising a non-enteric, water soluble polymer.

8. The particle of claim 1 further comprising a surfactant.

9. The particle of claim 1 wherein the weight ratio of enteric polymer to water insoluble film forming polymer in the coating is in the range of about 20:80 to about 80:20.

11. A chewable tablet comprising taste masked particles, each particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

12. The chewable tablet of claim 11, wherein the surfaces of the particles are substantially free of active ingredient.

13. The chewable tablet of claim 11, wherein the coating is substantially free of plasticizer.

14. The chewable tablet of claim 11, wherein the active ingredient is a nonsteroidal anti-inflammatory drug.

15. The chewable tablet of claim 11, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate and cellulose acetate phthalate.

16. The chewable tablet of claim 11, wherein the water insoluble film forming polymer is selected from the group consisting of cellulose acetate and ethylcellulose.

17. The chewable tablet of claim 11, wherein said coating further comprises an ingredient selected from the group consisting of non-enteric, water soluble polymers and surfactants.

18. The chewable tablet of claim 11, wherein the weight ratio of enteric polymer to water insoluble film forming polymer in the coating is in the range of about 20:80 to about 80:20.

19. A method of taste masking particles comprising an active ingredient, which comprises applying a continuous polymeric coating over said particles, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

21. The method of claim 19, wherein the coating is substantially free of plasticizer.

22. The method of claim 19, wherein the active ingredient is a nonsteroidal anti-inflammatory drug.

23. The method of claim 19, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate and cellulose acetate phthalate.

24. The method of claim 19, wherein the water insoluble film forming polymer is selected from the group consisting of cellulose acetate and ethylcellulose.